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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,516	10/29/2003	John D. Wagstaff	2314-271	8073

6449 7590 11/28/2006

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WASHINGTON, DC 20005

EXAMINER

HARLE, JENNIFER I

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,516

Applicant(s)

WAGSTAFF ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-26 are pending and subject to and Election/Restriction Requirement.

Election/Restrictions

2. The Election/Restriction Requirement dated March 13, 2006 is withdrawn.

Claim Objections

3. Claim 14 is objected to because of the following informalities: the word "aicy" should be "acid" in line 9. Appropriate correction is required.

4. Claim 14 objected to because of the following informalities: "un-glycosylated" should be "de-glycosylated" for consistency with the parent application, unless Applicants are trying to claim a different meaning. If Applicants are claiming a different meaning from the parent application, the examiner respectfully requests clarification of the definition. Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 1-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,489,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is almost identical in that it claims "A method for treating pain in an individual which comprises administering *an analgesic effective* amount of an active agent to an individual in need of pain treatment ..." whereas U.S. Patent No. 6,489,298 claims "A method for treating pain in an individual which comprises administering *a therapeutically effective* amount of an active agent to an individual in need of pain treatment ...". These terms are in fact considered equivalent for pain perception by Applicants as shown by their discussion in the Patent where they state "Analgesia, or the reduction of pain perception, can be effected directly by decreasing transmission along such nociceptive pathways. See col. 7, lines 26-28; [0043]. They also state that in one embodiment analgesia is induced in a mammal using one of the peptides described herein. See col. 3, lines 51-53; [0015]. Nowhere do they discuss treating pain separate from analgesia. The exact same language is used in the application and has been cited after the column and lines. Additionally, subparagraph (e) in the application substitutes at positions 1-9 and the patent substitutes at positions 2-9, as the position 1-9 is the preferred embodiment and is taught throughout the specification of the Patent. See col. 3, lines 38-40. Moreover, this is also an obvious embodiment given the limitations of subparagraphs (b), which would allow the modified O-glycan, S-glycan or N-glycan to be at any position. This is an obvious variation given The instant application's claims 1-12 and 14-24 are substantially identical in all other respects to claims 1-11 of U.S. Patent No. 6,489,298 – application claims 1-12 parallel patent claims 1(a) – 11 and application claims 14-24 parallel patent claims 1(b)-11. Claims 12-13 and 25-26 are obvious as being unpatentable over claim 1 of U.S. Patent No. 6,489,298 because it is obvious to choose

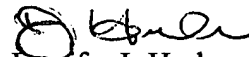
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preferred embodiments set forth in the specification for example claims 12 and 25 are clearly the most preferred glycans as set forth in col. 2, lines 54-56, and claims 13 and 26 are the analogs of the glycan which can be attached to one or more residues of the contulakin -G as demonstrated by Fig. 3, col. C, lines 66-67, col. 6, lines 33-44. The same support can be found in the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jennifer I. Harle
Examiner
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November 21, 2006

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